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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,840	07/25/2001	Robin Arthur Ellis Carr	PU3565USW	7700

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EXAMINER

SHIBUYA, MARK LANCE

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,840

Applicant(s)

CARR ET AL.

Examiner

Mark Shibuya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,10 and 12-31 is/are pending in the application.
- 4a) Of the above claim(s) 14-16,24-26 and 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,10,12,13,17-23 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claim 1, 3-6, 10, 12-31 are pending. Claims 14-16, 24-26 and 28-31 remain withdrawn. Claims 2, 7-9, 11 were cancelled in Amendment filed 4/14/2004. Claims 1, 3-6, 10, 12, 13, 17-23 and 27 are examined.

Election/Restrictions

2. Claims 14-16, 24-26 and 28-31 remain withdrawn from consideration by the examiner, as being drawn to non-elected species, there being no allowable generic claim.

Specification

3. Applicant's submission of a paper copy and a computer readable form of the Sequence Listing, filed 4/14/2004, is acknowledged. Applicant is advised that amendment to the specification identifying particular nucleic acid or amino acid sequences by SEQ ID No. is required.

Claim Objections

4. The objection to claim 1, as set forth in the previous Office action, mailed 10/16/2003, is withdrawn in view of applicant's amendments to the claim, filed 4/14/2004.

Claim Rejections - 35 USC § 112, First Paragraph

5. Claims 1, 3-6, 10, 12, 13, 17-23 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

This rejection maintains the rejection of claims 1-13, 17-23 and 27, as set forth in the previous Office action, mailed 10/16/2003.

The claims are drawn to a chemical construct for use in solid phase synthesis comprising: a solid support Q having linked thereto via a connecting group Y a substrate R; the connecting group Y having first and second cleavage sites which are orthogonally and selectively cleavable; the second cleavage site being selectively cleavable to release the substrate; and the first cleavage site being located at a position between the second cleavage site and the solid support and being selectively cleavable to release a fragment Fr comprising the substrate and at least a portion of the connecting group Y; and a moiety comprising a sensitizing G in masked form on the chemical fragment Fr at the first cleavage site wherein the chemical fragment Fr contains a means for imparting a characteristic signature to the mass spectrum of the fragment.

Response to Arguments

Applicant, in the Reply to the previous Office action, argues that the limitations of the claims are both adequately described and exemplified in the specification such that one skilled in the art would conclude that the applicant had possession of the invention. Applicant points the general descriptions of the invention found in pp 5-21 of the specification. Applicant points to examples and preferred limitations, including

substrates, linkers, fragments, sensitizing groups linking groups and spacer groups found on pages 22-25 of the specification.

Applicant's arguments filed 4/14/2004 have been fully considered but they are not persuasive. As stated in the previous Office action, applicant's claims are directed to a "chemical construct" that is defined in a completely functional manner and encompasses a wide variety of compounds. The specification does not provide examples that are representative of the full breadth of the claimed genus of chemical constructs. The claimed genus encompasses members that are yet to be prepared or envisioned in the context of the claimed invention. Thus the disclosure is inadequate to convey that applicant had possession of the full scope of the claimed invention.

Claim Rejections - 35 USC § 112, Second Paragraph

Withdrawn rejections

6. The rejection of claims 1-13, 17-23 and 27 under 35 U.S.C. 112, second paragraph in the previous Office action are withdrawn in view of applicant's amendments to the claims and applicant cancellation of claims 2, 7 and 9.

New Rejections

Claims 1, 3-6, 10, 12, 13, 17-23 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These rejections are necessitated by applicant's amendments to the claims, filed 4/14/2004.

Claim 1 does not have a period ending the claim. Correction is required.

Claim 5 recites the limitation "a characteristic signature" in line 2. There is uncertain antecedent basis for this limitation in the claim, because it is not clear if this "characteristic signature" is the same as that "characteristic signature" recited in line 12 of claim 1.

Claim 18 recites the limitation "the peak splitting isotopic label" in line. There is insufficient antecedent basis for this limitation in the claim.

Claim 22, as amended, recites the language: (iv) cleavage of enamine groups with a **1,2-bis;**", which does not make sense, because the previous following term "nucleophile" was deleted.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

7. Claims 1, 3-6, 10, 12, 13, 17-23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(1) as obvious over Carrasco et al. (Tet. Lett. 1997; on PTO-1449). This rejection maintains the rejection of claims 1-13, 17-23 and 27, as set forth in the previous Office action, mailed 10/16/2003.

The claims are drawn to a chemical construct for use in solid phase synthesis comprising: a solid support Q having linked thereto via a connecting group Y a substrate R; the connecting group Y having first and second cleavage sites which are orthogonally and selectively cleavable; the second cleavage site being selectively cleavable to release the substrate; and the first cleavage site being located at a position

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between the second cleavage site and the solid support and being selectively cleavable to release a fragment Fr comprising the substrate and at least a portion of the connecting group Y; and a moiety comprising a sensitizing G in masked form on the chemical fragment Fr at the first cleavage site wherein the chemical fragment Fr contains a means for imparting a characteristic signature to the mass spectrum of the fragment.

Response to Arguments

Applicant, in the Reply to the previous Office action, argues the reference of Carrasco does not teach, suggest or appreciate the present invention or its advantages. Applicant argues that Carrasco does not disclose that cleavage of the skeleton of the construct of the construct forms the sensitizing group G which sensitizes the chemical fragment. Applicant argues that Carrasco does not disclose the presence of the "masked form" of the sensitizing group as described in the specification and the amended claims.

Applicant's arguments filed 4/14/2004 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., cleavage of the skeleton of the construct forms the sensitizing group G which sensitizes the chemical fragment) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed.

Cir. 1993). It is respectfully submitted that such language is, itself, vague and indefinite. See previous Office action, mailed 10/16/2003, Rejection under 35 U.S.C. 112, second paragraph.

As stated in the previous Office action, the “derivatized resin” of Carrasco et al. incorporates a “dual linker strategy” where the “combination of the photocleavable linker and the ionization tag enables direct analysis of the beads by MALDI-MS” (reading on the claimed Fr group comprising a “sensitizing group G” and /or a means for imparting a characteristic signature to the mass spectrum of the fragment”). See Carrasco et al., Figure 1 and Scheme 1.

The instant Specification states:

The atoms or functional group making up the sensitizing group G can be present in a masked form in the construct before cleavage of the fragment Fr from the resin, the cleavage conditions merely serving to unmask the sensitizing group G.

Specification at p. 6, lines 25-27. Thus the sensitizing group G *can be present* in a masked form. Carrasco et al., in Figure 1 and Scheme 1, show an ionization sequence (which refers to the “sensitizing group G”) which is present in the resin-bound construct of Carrasco et al. Carrasco et al., at p. 6333, para 1, teaches that the desired peptides were “cleanly separated from the linker/ionization tag sequences, which appear by MALDI analysis to remain firmly attached to the resin.” Thus in giving “masked form” is broadest reasonable interpretation, the ionization tag sequences of Carrasco et al. can be said to be masked, until the desired peptides are cleanly separated away.

Conclusion

8. Claims 1, 3-6, 10, 12, 13, 17-23 and 27 stand finally rejected.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Shibuya
Examiner
Art Unit 1639

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